

WHAT IS CLAIMED IS:

1. A buccal spray composition for transmucosal administration of a pharmacologically active compound

provided that where the said active compound is soluble in a pharmacologically acceptable polar solvent said composition comprises in weight % of total composition: aqueous polar solvent 30-99.69%, active compound 0.001-60%,

where said composition additionally comprises a propellant said composition comprises in total weight % of total composition: a propellant selected from the group consisting of C₃₋₈ hydrocarbon of a linear or branched configuration :2 - 10%, aqueous polar solvent 10-99%, and active compound 0.1-25%,

where said active compound is soluble in a pharmacologically acceptable non-polar solvent said composition comprises in weight % of total composition: non-polar solvent 30-99.69%, active compound 0.005-55%, and

where said composition additionally comprises a pharmaceutically acceptable propellant said composition comprises in weight % of total composition: a propellant selected from the group consisting of C₃₋₈ hydrocarbon of a linear or branched configuration 5-80%, non-polar solvent 20-85%, active compound 0.05-50%,

wherein the active compound is selected from the group consisting of biologically active peptides, central nervous system active amines, sulfonyl ureas, antibiotics, antifungals, antivirals, sleep inducers, antiasthmatics, antiemetics, histamine H₂ receptor antagonists, barbiturates, prostoglandins, bronchial dilators selected from the group consisting of terbutaline, and theophylline.

2. The composition of claim 1 additionally comprising, by weight of total composition: flavoring agent 0.1-10%.

3. The composition of claim 1 comprising: polar solvent 37-98.58%, active compound 0.0005-55%, flavoring agent 0.5-8%.

4. The composition of claim 1 comprising: polar solvent 60.9-97.06%, active compound 0.01-40%, flavoring agent 0.75-7.5%.

5. The composition of Claim 1 wherein the polar solvent is selected from the group consisting of low molecular weight polyethylene-glycols (PEG) of 400-1000 MW, C₂-C₈ mono- and poly-alcohols, and alcohols of C₇-C₁₈ hydrocarbons of a linear or branched configuration.

6. The composition of Claim 1 wherein the solvent is aqueous polyethylene glycol.

7. The composition of Claim 1 wherein the solvent comprises aqueous ethanol.

8. The composition of Claim 1 wherein the active compound is selected from the group consisting of cyclosporin, clozapine, zidevudine, erythromycin, odansetron, cimetidine, phenytoin, carboprost thromethamine, and valenian in their nonionized form or as the pharmaceutically acceptable salts thereof.

9. The composition of Claim 2 wherein the flavoring agents are selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners and combinations thereof.

10. The composition of Claim 2 of the formulation: polar solvent 75-85%, cyclosporin 15-25%, flavoring agent 0.1-5%.

11. The composition of Claim 2 of the formulation: polar solvent 19-90%, odansetron hydrochloride 2.5-15%, flavoring agent 1-10%.

09537118-10000000

Sub
20

12. A method of administering a pharmacologically active compound to a mammal in need of same, by spraying the oral mucosa of said mammal with a composition of claim 1.

5 13. The method of claim 12 wherein the amount of spray administered is predetermined.

14. The composition of claim 1 comprising: propellant 5-80%, non-polar solvent 25-85%, active compound 0.1-40%, flavoring agent 1-8%.

10 15. The composition of claim 1 comprising: propellant 20-70%, non-polar solvent 30-74.75%, active compound 0.25-35%, flavoring agent 2-7.5%.

15 16. The composition of Claim 1 wherein the propellant is propane, N-butane, iso-butane, N-pentane, iso-pentane, or neo-pentane, and mixtures thereof.

20 17. The composition of Claim 1 wherein the propellant is n-butane or iso-butane and has a water content of no more than 0.2% and oxidizing agents, reducing agents, and Lewis acids or bases content in a concentration of less than 0.1%.

Sub 947
25 18. The composition of Claim 1 wherein the solvent is a selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydro-carbons of a linear or branched configuration, and C₂-C₆ alkanoyl esters, and triglycerides of the corresponding acids.

30 19. The composition of Claim 1 wherein the solvent is miglyol.

20. The composition of Claim 1 of the formulation: propellant 15-80%, non-polar solvent 20-85%, clozapine 0.5-30%, flavoring agent 1-5%.

[illegible]

5

10

15

20

2.5

QAC'

Add 57